



EUROPEAN
COMMISSION

Brussels, 6.7.2018
C(2018)4470 (final)

COMMISSION IMPLEMENTING DECISION

of 6.7.2018

**amending the marketing authorisation granted by Decision C(2004)3160 for “Ariclaim -
duloxetine hydrochloride”, a medicinal product for human use**

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use², and in particular Article 61(3) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Eli Lilly Nederland B.V. in accordance with Article 61(3) of Directive 2001/83/EC,

Whereas:

- (1) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.
- (2) Decision C(2004)3160 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.
- (3) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)3160 should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3160 is amended as follows:

- 1) Annex I is replaced by the text set out in Annex I to this Decision;
- 2) Annex II is replaced by the text set out in Annex II to this Decision;

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 311, 28.11.2001, p. 67.

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, Nederland.

Done at Brussels, 6.7.2018

For the Commission

Xavier PRATS MONNÉ

Director-General